UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,639	08/29/2001	Otto Gaa	RDID0092US	9431

7590 02/05/2004

Roche Diagnostics Corporation
9115 Hague Road, Bldg. D
P.O. Box 50457
Indianapolis, IN 46250-0457

EXAMINER	
GAKH, YELENA G	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,639	GAA ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *3 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The specification is objected to as not containing "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art" to use the invention in its bets mode. The specification is generally narrative and indefinite, failing to conform to current U.S. practice. It appears to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors.

The expression "method for checking the fitness for purpose of analysis elements", used throughout the disclosure, including the title, is grammatically incorrect and unclear. The explanation of the method, given in the following paragraph: "the invention relates to a method for checking the fitness for purpose of analysis elements, in which method a check is performed whether a measured control value for at least one control parameter of a checked analysis element is within a tolerance range" does not clarify the subject matter of the instant application. On page 4 the well known method of testing a test device (an analytical element, a test strip) comprising comparing a result of a blank measurement of the test strip with the reference value, with the following discarding the test strip, if the value is beyond the allowed range, is described. This appears to be the only clear explanation related to the method known in the art. Further elaboration of drawbacks of the method and the novel features of the present method are not apparent. Moreover, the specification refers to the claims, which is not a proper disclosure, since the claims should be relied on the specification (see pages 5 and 6). The disclosure is written in an unclear and indefinite language and is hard to comprehend.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

3. Claims 3 and 5 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 2 and 4. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

In claim 7 it is not clear, what is "showing a long-tern packaging common to all analysis elements"?

Claim 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is unclear and indefinite as to which elements the evaluation device comprises of, as no elements are listed in the body of the claim at all; there are numerous variations of conducting steps of the method recited in claim 1, especially since it is not clear from claim 1, which type of apparatus can be used for performing the steps of the method recited in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-6** are rejected under 35 U.S.C. 102(b) as being anticipated by Endoh et al. (US 4,436,812, IDS).

Endoh teaches "a process of calibrating a blood sugar analyzing apparatus, in which the blood sugar concentration in a blood specimen is measured with a fixed enzyme membrane sensor and corrected by calibration means, said blood sugar analyzing apparatus providing a linear relationship between measured and actual blood sugar concentrations in a range of blood sugar concentrations which are lower than a predetermined blood sugar concentration, and producing a deviation from said linear relationship in a range of blood sugar concentrations higher than said predetermined blood sugar concentration, in that said process comprises the steps of effecting a plurality of measurements of standard solutions having known low blood sugar concentrations in said blood sugar analyzing apparatus, obtaining an average value of the results of the measurements with said calibration means, determining a first correction coefficient (k.sub.1) to correct a deviation of said average value from the reference blood sugar concentration, thereafter measuring a blood specimen, and multiplying the result of the measurement by said correction coefficient with said calibration means when said result of the measurement is less than said predetermined blood sugar concentration and by a second calibration coefficient (K.sub.2) when the result of the measurement exceeds said predetermined blood sugar concentration" (Abstract), which covers the subject matter of claims 1-6.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 7-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Endoh in view of Hirai et al. (US 4,832,488) and Schreiber et al. (US 5,645,798, IDS) or Eihmeier et a. (US 5,720,924).

Endoh does not specifically disclose application of his method for evaluating suitability ("fitness") of dry test strips contained separately in a container.

Hirai discloses a method for correction of calibration curve for dry test strips. Hirai does not specifically disclose plurality of dry test strips contained separately in the container.

Schreiber or Eihmeier discloses plurality of test strips contained separately in the container.

It would have been obvious for anyone of ordinary skill in the art to apply Endoh's method to Hirai's system, for which analogous method was developed, because Endoh's method has obvious advantages regarding evaluation of the analytical apparatus for different ranges of

the analyte (glucose) concentration. It would have been obvious for anyone of ordinary skill in the art to apply Endoh-Hirai's method to the test strips separately contained in the container, as disclosed by Schreiber or Eihmeier, because storing the test elements in the cotainer requires their periodic evaluation. It would have been obvious for anyone of ordinary skill n the art to automate, since automation is usually used when dealing with plurality of similar tests.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Fuller et al. (US 5,174,963 and US 5,277,870)* disclose a "blood glucose reflectance meter including a null prompting means and a device for providing a constant brightness light"; *Freeman et al. (US 5,258,308)* teach "method, kit and apparatus for verifying calibration and linearity of vertical photometers"; *Anderson et al. (US 5,279,294)* disclose a "medical diagnostic system" for quantitative measurement of glucose in biological fluids with verification and calibration means; *Matzinger et al. (US 5,780,304)* teach a "method and apparatus for analyte detection having on-strip standard"; *Geisberg (US 6,103,536)* disclose "internally referenced competitive assays".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1700.

Yelena G. Gakh
1/26/04